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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,320	01/18/2002	H. Michael Shepard	NB 2019.00	8000
7590	03/02/2005			
McCutchen, Doyle, Brown & Enersen LLP Suite 1800 Three Embarcadero Center San Francisco, CA 94111			EXAMINER KIM, JENNIFER M	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/051,320	Applicant(s) SHEPARD, H. MICHAEL	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/22/04, 12/08/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 5-9 and 11-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/22/04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 11/22/2004 and 12/8/2004 has been entered.

Action Summary

The objection of claim 11 as being failing to clearly set forth Applicants' invention of treating rheumatoid arthritis with phosphoramedatyl deoxyuridine compounds set forth in the specification is hereby expressly withdrawn in view of Applicant's amendment.

The rejection of claims 1, 4, 10 and 13 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicants amendment.

Applicant's remarks with respect to claims 1 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lackey et al. (Biochemical Pharmacology, 2001) in view of Applicant's admission.

Lackey et al. teach Applicant's active agent (E)-5-(2-Bromovinyl)-2'-deoxy-5'-uridyl phenyl L- methoxyalaninylphosphoramidate (also known as NB1011) has cytotoxic activity against tumor cell lines. (abstract, page 181-185, particularly, page 185 under 3.5). Lackey et al. teach on page 181 under paragraph 2.7, that NB 1011 was administered 1.25, 2.5 and 3.5 mg total dose/animal/day which is within Applicants effective dosage set forth in claims 1 and 20 as disclosed in the specification page 10, lines 1-5.

Lackey et al. do not teach the treatment of rheumatoid arthritis or an L- or D-form of NB1011.

Applicant admits on page 1, under background [0003] that the function of tumor suppressor genes is a major focus of recent attempts to develop innovative therapeutics for the treatment cancer. Applicant also admits that the functional loss of tumor suppressor genes also has been linked to hyperproliferative inflammatory or

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autoimmune disease including rheumatoid arthritis that have cellular hyperproliferation as one of their characteristic.

It would have been obvious to one of ordinary skill in the art to employ NB1011 for the treatment of rheumatoid arthritis because as Applicant admits that rheumatoid arthritis and cancer both have same cellular hyperproliferation characteristics and both of the disorders are related as losing functions of tumor suppressor genes. One would have been motivated to employ NB1011 for the treatment of rheumatoid arthritis in order to target cellular hyperproliferation characteristics and avoid losing functions of tumor suppressor genes in rheumatoid arthritis by administering cytotoxic, antitumor (antiproliferative) compound (NB1011) as taught by Lackey.

Regarding the L- or D-compound of NB1011 is obvious since one skilled in the art expects that a compounds in general exist in more than one racemic form and selection of any one of existing racemic form of a compound is considered obvious to one of ordinary skill in the relevant art. The racemic form of a compound has been held to be within this general principal. In re Anthony, 414 F. 2d 1383, 162 USPQ 594 (CCPA 1969); Brenner v. Ladd, 247 F. Supp. 51, 147 USPQ 87 (1965).


For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
February 24, 2005